

REMARKS

Upon entry of the foregoing amendment, claims 1-15, 18, and 20-87 are pending for the Examiner's consideration, with claims 1, 20, 29, 30, 49, 50, 60, 63, 71, and 74 being the independent claims. Claims 16, 17, and 19 are canceled herein, without prejudice to or disclaimer of the subject matter contained therein. Claims 1, 20, 29, 30, 49, 50, 60, 63, and 71 are amended herein. Applicants respectfully submit that these amendments introduce no new matter. The Examiner is referred to in this regard, for example, paragraphs 0066-0068, and Figures 1 and 2, as well as the description thereof, in the application as originally filed.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-30, 32-50, 52, 54-60, 63-69, and 71-87 under 35 U.S.C. § 103(a) as being unpatentable over WO 89/03678 ("the Lewis *et al.* PCT") in view of U.S. Patent No. 4,389,330 to Tice *et al.* ("the '330 patent"), Handbook of Chemistry and Physics ("the Hodgman *et al.* reference"), U.S. Patent No. 4,737,437 to Gutsell, Jr. *et al.* ("the '437 patent"), and U.S. Patent No. 5,989,463 to Tracy *et al.* ("the '463 patent"). Claims 1, 20, 29, 30, 49, 50, 60, 63, and 71 are amended herein, thereby rendering this rejection moot as to these claims and those depending therefrom.

The teachings of the Lewis *et al.* PCT, the '330 patent, and the '463 patent relied upon by the Examiner are all directed to removing solvents from microparticles prior to obtaining a finished microparticle product. For example, the Lewis *et al.* PCT explains on the bottom of page 5 that "[a]fter the quenching step, the microsphere product is collected and dried under a vacuum to reduce the level of organic solvent in the final microsphere product." Similarly, in the '330 patent, the "washing" is the second part of solvent removal after solvent evaporation, and a final product is obtained after removal of water and drying. Finally, in the '463 patent, the mixture of heptane and ethanol is used as a "cure phase" to extract solvent, and the microparticles are then separated and freeze-dried.

In contrast, the present invention is directed to a washing process that is carried out on a finished microparticle product (*see*, for example, paragraphs 0066-0068 of the application as originally filed). In particular, independent claims 1, 30, 49, 60, and 63 as presented herein

are directed to a method for preparing microparticles that includes a washing step that is performed on finished microparticles, after the precipitated microparticles are dried. Similarly, independent claims 20, 29, 50, and 71 have been amended herein to recite a method for processing microparticles that includes a step of contacting dried, finished microparticles with the washing system to form washed microparticles.

None of the documents cited by the Examiner teaches or suggests a washing step that is carried out after drying the microparticles, or one that is carried out on dried, finished microparticles. As recognized by the Examiner on page 3 of the Office Action, the Lewis *et al.* PCT does not teach washing the microcapsules as a final step. Rather, the Lewis *et al.* PCT explains on the bottom of page 5 that the microsphere product is collected and dried under vacuum after the quenching step. This is similar to the process used in the '330 patent, where the "washing" is the second part of solvent removal after solvent evaporation, and a final product is obtained only after removal of water and drying. Even if the teachings of the Lewis *et al.* PCT are combined with the teachings of the '330 patent and the other documents cited by the Examiner, the claimed invention does not result because there is no teaching or suggestion of washing dried microparticles to further reduce solvent levels after a dried, finished product has been obtained. For at least the foregoing reasons, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) cannot properly be maintained for independent claims 1, 20, 29, 30, 49, 50, 60, 63, and 71 as presented herein, and the more narrow dependent claims depending therefrom.

Independent claim 74 is directed to a process for preparing microparticles that uses a solvent blend of a hardening solvent and a washing solvent to extract solvent from the emulsion combined phase, and to form hardened microparticles in a single step. None of the documents cited by the Examiner discloses or suggests the use of a solvent blend of a hardening solvent and a washing solvent to do solvent extraction and hardening of the coacervate into microparticles in a single step. For at least this reason, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) cannot properly be maintained for independent claim 74, and the more narrow dependent claims depending therefrom.

The Examiner's rejections of dependent claims 31, 51, 53, 61, 62, and 70 are rendered moot in light of the amendments to the independent claims from which they depend, and in light of the discussion above with respect to the independent claims. As such, these rejections will not be separately discussed, and Applicants do not concede the propriety of any of the rejections made by the Examiner.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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